

REMARKS

This amendment accompanies the filing of a Request for Continued Examination.

In the Office Action of October 19, 2006, all of pending claims 76-78, 80-86, 89-94, and 105-108 stand rejected. All of these pending claims are canceled by the present amendment and replaced with new claims 109-136. New claims 109-136 are fully supported by the specification and the drawings as originally filed. The subject matter of claims 109-125 is best illustrated in Figs. 2 and 3, while the subject matter of claims 126-136 is best illustrated in Figs. 2-4.

Independent claim 109 recites "a method of producing a plurality of sterilized, prefilled containers comprising: providing a plurality of separate manufacturing lines; providing each manufacturing line with at least one container; transferring the containers along the manufacturing lines into a common sterile environment from a location exterior to the sterile environment; introducing a sterile fluid substance into the containers while the containers are within the common sterile environment; sealing the sterile fluid substance within the containers while the containers are within the common sterile environment; and transferring the containers out of the common sterile environment, wherein said manufacturing lines remain separate during the step of transferring the containers out of the sterile environment." It is respectfully submitted that claim 109 is patentable at least for the reason that the references cited by the Examiner fail to teach or suggest a method incorporating a plurality of manufacturing lines that are separate before and after entering a common sterile environment.

U.S. Patent No. 6,145,277 (Lawnecki et al.) describes a configuration whereby two

conveyors 74 feed syringe barrels to a packaging isolation module 14 with a single output line (Fig. 7). First, the enclosure 10 of Lawecki et al. is a single sterile environment, so the syringe barrels are never transferred into a common sterile environment from a location exterior to the sterile environment, as required by claim 109. Second, the manufacturing lines of Lawecki et al. merge into a single processing line before the syringe barrels are transferred out of the enclosure 10, in contrast to the requirements of claim 109. The remaining references cited by the Examiner fail to teach or otherwise suggest a method whereby containers are moved out of a sterile environment using a plurality of manufacturing lines. For at least these reasons, it is respectfully submitted that independent claim 109 and all claims dependent therefrom are patentable.

Independent claim 126 recites "a method of producing a sterilized, prefilled container comprising: providing a container; sterilizing the container at a sterilizing station; transporting the container along a transport mechanism from the sterilizing station and into a sterile environment that is separate from the sterilizing station; providing a sterile ambient atmospheric condition external and adjacent to the sterile environment, wherein at least a portion of the sterile ambient atmospheric condition is provided by the sterilizing station and said transporting the container includes exposing the container to the sterile ambient atmospheric condition; introducing a sterile fluid substance into the container while the container is within the sterile environment; and sealing the sterile fluid substance within the container while the container is within the sterile environment." It is respectfully submitted that claim 126 is neither anticipated nor

made obvious by the prior art of record.

U.S. Patent Nos. 3,780,308 ("Nablo") and 6,334,472 ("Lemke et al.") describe arrangements for providing a sterile condition at the entrance to a sterile environment, but neither of these references teaches or suggests a method that includes a separate sterilizing station, a sterile ambient atmospheric condition external to the sterile environment, or the use of the sterilizing station to provide at least a portion of the sterile ambient atmospheric condition. U.S. Patent Nos. 4,014,158 ("Rausing") and 6,800,245 ("Erbe et al.") disclose containers that may be sterilized before introducing them into a sterile environment, but there is no discussion of the manner in which the containers are maintained in a sterile condition between the pre-sterilizing stage and the filling stage in the sterile environment. There is certainly no teaching or suggestion that the pre-sterilizing stage may be used to provide at least a portion of a sterile ambient atmospheric condition external and adjacent to the sterile environment. Accordingly, it is respectfully submitted that independent claim 126 and all claims dependent therefrom are patentable for at least the preceding reasons.

CONCLUSION

For the above reasons, it is respectfully submitted that all of the claims are in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested. Please charge deposit account 50/1039 for any fees required by this amendment.

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Respectfully submitted,

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